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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	18

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/963,848	FRENCH ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-90* is/are pending in the application.

4a) Of the above claim(s) *24,26-33,36,42-44,46,47,50-86 and 90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,25,34,35,37-41,45,48,49 and 87-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 11/17/03 has been entered as Paper No. 17. Claims 91-95 have been canceled and the changes made to Figure 21, specification and claims (those that are being considered for examination) have been considered and approved by the examiner. The replacement sheet and annotated sheet showing the required changes to Figure 22A was not included with the amendment, so the objection to the drawing has been maintained. The examiner requests that these two sheets be included with the response to this office action. Claims 1-90 are pending; claims 24, 26-33, 36, 42-44, 46, 47, 50-86 and 90 remain withdrawn from consideration; claims 1-23, 25, 34, 35, 37-41, 45, 48, 49 and 87-89 are being considered for further examination on the merits.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "xiphoid process (510)", as mentioned on page 21, line 4, should be shown in Figure 22A. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-6, 12-15, 18, 23, 25, 34, 35, 37-41, 45, 48, 49 and 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Snyders (USPN 6,095,968 as cited in previous office action).

Snyders discloses a pericardial reinforcement with all the elements of claim 1. See Figure 2 for the pericardial reinforcement (10) comprising an enclosure generally conforming in shape to at least a portion of the heart (column 1, lines 36-42; column 3, lines 5-8; column 6, lines 45-48; Figure 3). The enclosure consists essentially of a compliant and substantially non-elastic member (combination of 12 and 13) having an interior surface (interior surface of 13) for placement adjacent an epicardium, the interior surface tending to inhibit adhesions with the epicardium (columns 3-4, lines 65-4) and having an exterior surface (exterior surface of 12) which is capable of being attached to the inside of a pericardium (column 3, lines 5-17). The phrase "for attachment" is functional language, so the claim only requires that the exterior surface be *capable* of being attached to the inside of a pericardium, which it is.

Claims 2-6, see column 4, lines 1-4 and Figure 5 for the interior surface comprising a lubricious polymeric (column 3, lines 24-27) material, wherein the friction-reducing coating on the interior surface and steroid dispersion inherently resist ingrowth with the epicardium.

Claims 12-15, 18, 23 and 34, see column 3, lines 7-17 and column 4, lines 60-63 for exterior surface being of woven Dacron (polymeric), which by nature promotes endothelialization, allows for ingrowth into, attachment to, and adherence with the pericardium.

Claim 25, see Figure 2 for exterior surface material comprising a non-woven (16) polymeric material (column 5, lines 14-21).

Claims 35 and 37-41, see column 3, lines 1-17 and columns 4-5, lines 60-21 for compliant and substantially non-elastic member comprising an inner member (13) and an outer member (12) of separate layers of woven or non-woven fabrics laminated together at their margins, the outer member comprising a non-woven fabric (16).

Claim 45, see Figure 2 for band (5).

Claims 48 and 49, see Figure 5 and column 2, lines 19-23 for sack having a closed end.

Claims 87-89, see columns 2-3, lines 55-1 and column 6, lines 60-65 for method of reinforcing the pericardium.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7-9, 11 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders in view of Alferness (USPN 6,241,654 as cited in applicant's IDS).

Snyders discloses a pericardial reinforcement with all the elements of claim 1, but is silent to the interior surface being the fluorocarbon polymers PTFE or ePTFE or the polymer polypropylene, as required by claims 7-9 and 11, and the exterior surface being polyethylene terephthalate or ePTFE, as required by claims 19-21. Alferness teaches a cardiac reinforcement device that can be placed under the parietal pericardium (column 10, lines 31-33) made of PTFE, ePTFE, polypropylene or polyethylene terephthalate (polyester) because these materials are physiologically inert to minimize an immune reaction or other excessive inflammatory response. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Alferness to modify the pericardial reinforcement of Snyders by making the interior surface of PTFE, ePTFE or polypropylene and the exterior surface of ePTFE or polyethylene terephthalate (polyester) because these material are well known in the art to be physiologically inert and minimize an immune reaction or other excessive inflammatory response. See columns 6-7, lines 62-2.

7. Claims 10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders and Alferness as applied to claims 7, 19 and 21 above, and further in view of Martakos et al. (USPN 5,897,587 as cited in previous office action).

Snyders, as modified by Alferness, discloses a pericardial reinforcement with all the elements of claim 7, but is silent to the interior and exterior ePTFE surfaces having internodal spacings of less than about 40 microns and greater than about 60 microns, respectively, as required by claims 10 and 22, respectively. Martakos et al. teaches a multistage PTFE prosthesis wherein one section has an internodal spacing of less than about 40 microns in order to prevent

encapsulation and another section has an internodal spacing of greater than about 60 microns in order to allow for tissue ingrowth during healing. See column 3, lines 3-20. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Martakos et al. to modify the pericardial reinforcement of Snyders and Alferness by making the interior surface have an internodal spacing of less than about 40 microns in order to further prevent encapsulation of the surface, which already has coating that inhibits ingrowth with the epicardium. It would have been obvious to make the exterior surface have an internodal spacing of greater than about 60 microns in order to allow for tissue ingrowth with the pericardium to strengthen the attachment therebetween.

8. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders in view of Williams et al. (USPN 5,131,907 as cited in previous office action).

Snyders discloses a pericardial reinforcement with all the elements of claim 1, but is silent to the material promoting endothelialization comprising an effective hyaluronate salt or an angiogenic material, as required by claims 16 and 17, respectively. Williams et al. teaches that it is old and well known in the art to use fibronectin hyaluronate for adhering fibroblasts to an implant by citing Laterra et al. See column 7, lines 9-11. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to Williams et al. for the disclosure of using hyaluronate for adhering cells to an implant as being old and well known the art in order to modify the pericardial reinforcement of Snyders by using appropriate hyaluronate to promote endothelialization. Williams et al. also teaches treating an implant substrate material with collagen (angiogenic material) in order to improve human endothelial cell adhesion. See

column 7, lines 37-42. It would have been obvious to one of ordinary skill in the art to look to the teachings of Williams et al. to modify the pericardial reinforcement of Snyders by including into the exterior surface the angiogenic material collagen in order to improve human endothelial cell adhesion. Promoting endothelialization will increase the strength of attachment between the pericardial reinforcement and the pericardium.

Response to Arguments

9. Applicant's arguments filed 11/17/03 have been fully considered but they are not persuasive.

10. The examiner disagrees with applicant's summary of the reinforcement device of Snyders. Fluid is not pumped in and out of the region between the inner and outer surfaces in order to compress the ventricles of the heart through assisted pumping. The reinforcement device is static, wherein the instillation of a high viscosity silicone or other non-compressible fluid into the retention sac between inner sheath (13) and outer shell wall (12) encloses the ventricular masses with either no or minimal pressurization therein. This results in a viscous cardioplasty reinforcement of the thinned ventricular walls with a resultant reduction in left and right ventricular diameters to effect a desirable reduction of wall stress, which provides for "reverse modeling" of the heart via both a diastolic and systolic volumetric restriction. See column 1, lines 42-54 and column 3, lines 17-23.

11. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the device is an integrated or laminated structure wherein there is no intention of the inner and outer layers to

be separated from each other) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. Applicant argues that in contrast to the device of claim 1, which requires "A compliant and substantially non-elastic pericardial reinforcement...", the device of Snyders must be elastic on its inner surface in order to fulfill the pumping function described. In response, the examiner would first like to point out that there is no pumping function of the Snyders device, as explained above. Second, applicant defines in [0040] of the specification that the term "substantially non-elastic" is used "simply to express the functional concept that during the use of the device in reinforcing the pericardium, the device is not substantially changing in size due to the pressures placed upon it by the beating of the heart". So although the inner flexible sac liner (13) portion of the enclosure is elastic by material make-up, it is "substantially non-elastic" by function because it is not substantially changing in size. Therefore, the device of Snyders meets the limitations of claim 1 as defined.

13. Applicant argues that the addition of the limitation "an enclosure generally conforming in shape to at least a portion of the heart, said enclosure consisting essentially of" excludes two-component enclosure systems, such as described by Snyders. The examiner disagrees. The enclosure of Snyders is indeed consisting essentially of a compliant and substantially non-elastic member, wherein the member is the combination of inner sheath (13) and outer shell wall (12). This member (12, 13) does indeed generally conform in shape to at least a portion of the heart (see Figures 3 and 5, for example).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

Urmi Chattopadhyay
Art Unit 3738

David J. Isabella
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